

WE CLAIM:

1. A pharmaceutical composition for oral administration, comprising:
 - a. lithium carbonate,
 - b. optional pharmacologic excipients,
 - c. at least one dissolution rate stabilizer, and
 - d. at least one secondary release agent.
- 5 2. The pharmaceutical composition according to claim 1, wherein the lithium carbonate does not exceed a dose greater than about 450 mg/tablet.
- 10 3. The pharmacologic composition according to claim 1 additionally comprising iron oxide as a colorant, wherein the iron oxide does not exceed a level of about 1 mg/tablet.
- 15 4. The pharmaceutical composition according to claim 1, wherein the optional pharmacologic excipients further comprises at least one lubricant at a concentration of between about 0.1% and about 1.0% of the composition by weight.
- 5 20 5. The pharmaceutical composition according to claim 4 wherein said lubricant is selected from stearic acid, calcium stearate, magnesium stearate and sodium stearyl fumerate, said lubricant is at a concentration of about 0.1% to about 1.0% of the composition by weight.

6. The pharmaceutical composition according to claim 1, wherein the composition is compressed at a pressure of between about 7kPa to about 20 kPa.
7. The pharmaceutical composition according to claim 1, wherein the composition is
5 compressed with a pressure not greater than about 7 kPa.
8. The pharmaceutical composition according to claim 1, wherein the at least one dissolution rate stabilizer comprises sodium carboxymethylcellulose.
- 10 9. The pharmaceutical composition according to claim 8, wherein the sodium carboxymethylcellulose comprises between about 5% to about 15% of the composition by weight.
- 15 10. The pharmaceutical composition according to claim 8, wherein the sodium carboxymethylcellulose comprises not more than about 5% of the composition by weight.
11. The pharmaceutical composition according to claim 1, wherein the at least one secondary release agent comprises glycine.
- 20 12. The pharmaceutical composition according to claim 11, wherein the glycine comprises between about 0.5 to about 40 mg/tablet.

13. The pharmaceutical composition according to claim 11, wherein the glycine comprises a level not greater than about 20 mg/tablet.
14. The pharmaceutical composition according to claim 11, wherein the glycine comprises a 5 level not greater than about 14 mg/tablet.
15. The pharmaceutical composition according to claim 11, wherein the glycine comprises a level not greater than about 11 mg/tablet.
- 10 16. The pharmaceutical composition according to claim 11, wherein the glycine comprises a level not greater than about 2 mg/tablet.
17. A pharmaceutical composition for oral administration, comprising:
- 15 a. lithium carbonate,
 - b. iron oxide,
 - c. stearic acid,
 - d. sodium carboxymethylcellulose,
 - e. glycine and
 - f. optional pharmaceutically acceptable excipients.
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18. A controlled release solid dosage form of lithium carbonate containing:
- a. about 85% to about 90% by weight lithium carbonate,
 - b. about 10% to about 15% sodium carboxymethylcellulose,

- c. about 0.5% glycine, and
- d. optional pharmaceutically acceptable excipients.

19. A process for preparing a controlled release solid dosage form of lithium carbonate in
5 accordance to claim 1, which comprises the steps of:

- a. mixing lithium carbonate and iron oxide into a blend;
- b. solubilizing a solution of water, sodium carboxymethylcellulose, and at least one secondary release agent;
- c. placing the blend of lithium carbonate and iron oxide in a bed of a fluid bed granulator;
- 10 d. creating a top sprayed blend by spraying the solution onto the blend in the bed of the fluid bed granulator;
- e. granulating the top sprayed blend in the fluid bed granulator into a granulation;
- f. forming a composition by milling the granulation with at least one excipient; and
- g. pressing the granulation with at least one excipient into tablets in a tablet press.

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20. The process according to claim 19, wherein the at least one excipient comprises at least one lubricant.

21. The process according to claim 20, wherein the at least one lubricant is selected from the
20 group consisting of stearic acid, sodium stearyl fumerate, calcium stearate, and magnesium stearate.

22. The process according to claim 21, wherein the secondary release agent comprises glycine.

23. A pharmaceutical composition for oral administration prepared according to claim 22.
24. A method for the treatment of Bipolar Disorder consisting essentially of orally administering
5 to a patient a therapeutically effective amount of a composition according to claim 1.
25. A method for the treatment of Manic - Depressive Disorder consisting essentially of orally
administering to a patient a therapeutically effective amount of a composition according to
claim 23.

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26. A method for the treatment of Bipolar Disorder consisting essentially of orally administering
to a patient a therapeutically effective amount of a controlled release solid dosage form of
lithium carbonate according to claim 8.

- 15 27. A process for manufacturing a pharmaceutical composition for oral administration , which
comprises the steps of:
- a. mixing lithium carbonate and iron oxide into a first blend,
- b. solubilizing a first solution of water and sodium
carboxymethylcellulose,
- c. reserving a quantity of the first blend equal to create a
second blend,
- d. placing the first blend of lithium carbonate in a bed of a
fluid bed granulator,
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- e. dissolving the second blend in the first solution of water and sodium carboxymethylcellulose to form a second solution,
- f. creating a top sprayed blend by top spraying the second solution onto the first blend in the bed of the fluid bed granulator,
- g. granulating the top sprayed blend in the fluid bed granulator into a granulation,
- h. milling the granulation with at least one excipient, and
- i. pressing the granulation with at least one excipient composition into tablets in a tablet press.

28. The process according to claim 27 wherein the at least one excipient comprises at least one lubricant.

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29. The process according to claim 28, wherein the at least one lubricant is selected from the group consisting of stearic acid, sodium stearyl fumerate, calcium stearate, and magnesium stearate.

20 30. A pharmaceutical composition for oral administration prepared according to claim 27.

31. A pharmaceutical composition for oral administration prepared according to claim 28.

32. A pharmaceutical composition for oral administration prepared according to claim 29.

33. A method for the treatment of Bipolar Disorder consisting essentially of orally administering to a patient a therapeutically effective amount of a composition according to claim 30.

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34. A method for the treatment of Manic - Depressive Disorder consisting essentially of orally administering to a patient a therapeutically effective amount of a composition according to claim 31.

10 35. A method for the treatment of Bipolar Disorder consisting essentially of orally administering to a patient a therapeutically effective amount of a composition according to claim 32.

36. A pharmaceutical composition for oral administration, comprising:

- a. lithium carbonate,
- 15 b. optional pharmacological excipients, and
- c. at least one dissolution rate stabilizer.

37. The pharmaceutical composition according to claim 36, wherein the lithium carbonate does not exceed a dose greater than about 450 mg/tablet.

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38. The pharmacologic composition according to claim 36, additionally comprising iron oxide as a colorant, wherein the iron oxide does not exceed a level of about 1 mg/tablet.

39. The pharmacologic composition of claim 36, wherein the optional pharmacologic excipients further comprises at least one lubricant.

40. The pharmaceutical composition according to claim 39, wherein the at least one lubricant
5 further comprises stearic acid at 0.1% to about 5.0% of the composition by weight.

41. The pharmaceutical composition according to claim 40, wherein the at least one lubricant further comprises stearic acid at a level consisting of not more than about 0.5% of the composition by weight.

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42. The pharmaceutical composition according to claim 39, wherein the at least one lubricant further comprises sodium stearyl fumerate.

43. The pharmaceutical composition according to claim 42, wherein the at least one lubricant
15 further comprises sodium stearyl fumerate at a level of about 0.1% to about 1.0% of the composition by weight.

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44. The pharmaceutical composition according to claim 43, wherein the at least one lubricant further comprises sodium stearyl fumerate at a level consisting of not more than about 0.5% of the composition by weight.

45. The pharmaceutical composition according to claim 39, wherein the at least one lubricant further comprises calcium stearate at a level of about 0.1% to about 1.0% of the composition by weight.

5 46. The pharmaceutical composition according to claim 39, wherein the at least one lubricant further comprises magnesium stearate at a level of about 0.1% to about 1.0% of the composition by weight.

10 47. The pharmaceutical composition according to claim 36, wherein the composition is compressed at a hardness of between about 7kPa to about 20 kPa.

48. The pharmaceutical composition according to claim 36, wherein the composition is compressed at a pressure not greater than about 7 kPa.

15 49. The pharmacologic composition according to claim 36, wherein the at least one dissolution rate stabilizer comprises sodium carboxymethylcellulose.

50. The pharmaceutical composition according to claim 49, wherein the sodium carboxymethylcellulose comprises between about 5% to about 15% of the composition by 20 weight.

51. The pharmaceutical composition according to claim 49, wherein the sodium carboxymethylcellulose comprises not more than about 10% of the composition by weight.

52. The pharmaceutical composition according to claim 49, wherein the sodium carboxymethylcellulose comprises not more than about 5% of the composition by weight.

5 53. A pharmaceutical composition for oral administration, comprising:

- a. about 85% to about 90% by weight lithium carbonate,
- b. about 10% to about 15% sodium carboxymethylcellulose,
- c. iron oxide,
- d. stearic acid, and
- 10 e. optional pharmaceutically acceptable excipients.

54. A process for manufacturing a pharmaceutical composition for oral administration, in accordance with claim 53, which comprises the steps of:

- a. mixing lithium carbonate and iron oxide into a blend,
- 15 b. solubilizing a solution of water and sodium carboxymethylcellulose,
- c. placing the blend of lithium carbonate and iron oxide in a bed of a fluid bed granulator,
- d. creating a granulation by top spraying the solution onto the blend in the bed of the fluid bed granulator,
- 20 e. forming a composition by milling the granulation with at least one excipient, and

f. pressing the granulation with at least one excipient composition into tablets in a tablet press.

55. The process according to claim 54 wherein the at least one excipient comprises at least one
5 lubricant.

56. The process of claim 54, wherein the at least one excipient is a lubricant selected from the group consisting of stearic acid, sodium stearyl fumerate, calcium stearate, and magnesium stearate.

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57. A pharmaceutical composition for oral administration prepared according to claim 54.

58. A pharmaceutical composition for oral administration prepared according to claim 55.

15 59. A method for the treatment of Bipolar Disorder (Manic - Depressive Disorder) consisting essentially of orally administering to a patient a therapeutically effective amount of a composition according to claim 36.

20 60. A method for the treatment of Bipolar Disorder (Manic - Depressive Disorder) consisting essentially of orally administering to a patient a therapeutically effective amount of a composition according to claim 53.